

REMARKS

The present application contains claims 1-155, the status of which is as follows:

- (a) Claims 1-139 have been cancelled without prejudice.
- (b) Claims 140-155 are new.

The Applicant thanks Examiners Araj and Robert for the courtesy of an interview with the Applicant's representative, Sanford T. Colb (Reg. No. 26,856) on March 5, 2008. The Applicant's representative, Sanford T. Colb (reg. no. 26,856), discussed the patentability of claim 1 as originally filed. Mr. Colb brought a working model of the nail (30) and sleeve (50) as shown in Figs. 2A, 2B, and 3, and as described in the text of the present patent application. As shown during a demonstration, when the sleeve was inserted into the nail and rotated until the locking mechanism engaged, rotation and axial movement of the sleeve with respect to the nail was prevented. In order to overcome Lawes, the Examiners suggested that claim 1 as filed be amended to add "said intramedullary nail having a locking surface that has an indent which prevents rotational and longitudinal movement between the sleeve and the hole." The Examiners noted that further search and consideration of this amended claim would be necessary.

New claim 140 is based on claim 1 as filed, and additionally includes the amendment substantially as suggested during the interview (modified slightly by the Applicant in this response to integrate more easily into the language of claim 1 as filed and to recite that both inward and outward longitudinal movement is prevented). Claim 140 reads as follows, with underlined text showing insertions and strikethrough showing deletions with respect to claim 1 as originally filed.

140. (new) Apparatus for treating a fracture of a bone of a subject, comprising:

an intramedullary (IM) nail, adapted to be inserted in a medullary canal of the bone of the subject, and comprising a proximal head that defines at least one hole therethrough, the intramedullary nail having a locking surface shaped to define an indent; and

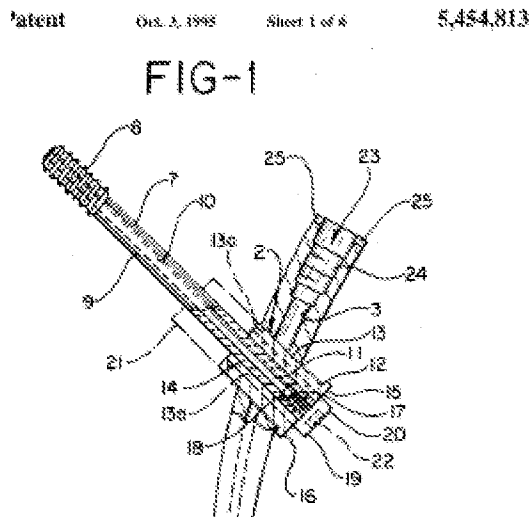
a sleeve, comprising a locking mechanism, which locking mechanism is adapted to engage the ~~hole~~ indent of the locking surface of the intramedullary nail when the sleeve is inserted in the hole, such engagement preventing rotational movement between the sleeve and

the nail and preventing both inward and outward longitudinal movement between the sleeve and the nail.

The Applicant believes that none of the references of record or otherwise known to the Applicant describe or suggest the apparatus of claim 140.

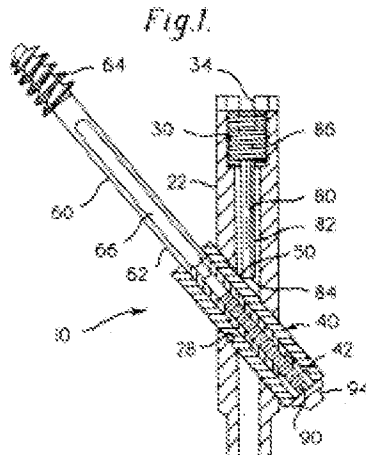
(a) Claim 140 recites, *inter alia*, that the engagement of the locking mechanism of the sleeve to the hole prevents both inward and outward longitudinal movement between the sleeve and the hole.

Apparatus described in US 5,454,813 to Lawes, by contrast, does not prevent longitudinal movement, as recited in claim 140. Fig. 1 of Lawes shows:



As Lawes describes with reference to Fig. 1, "...proximal end 15 of sleeve 12 is provided with a shoulder 16." Since longitudinal movement (down and right in the figure) is allowed by the engagement between the sleeve and the hole in the nail, Lawes therefore does not anticipate the recited limitation of claim 140 of the locking mechanism engaging the indent of the locking surface, such engagement preventing both inward and outward longitudinal movement between the sleeve and the nail of claim 140.

(b) Much of the prior art describes securing a sleeve to a nail by using a set screw coming down through the top of the nail. See, for example, set screw 80 in Fig. 1 of US 5,032,125 to Durham (cited in the Background of the present application):



Such a set screw does not anticipate or suggest "a sleeve, comprising a locking mechanism, which locking mechanism is adapted to engage the indent of the locking surface of the intramedullary nail when the sleeve is inserted in the hole, such engagement preventing rotational movement between the sleeve and the nail and preventing both inward and outward longitudinal movement between the sleeve and the nail" as recited in claim 140. Claim 140 recites characteristics of a sleeve, and how the sleeve engages the hole in the nail. The prior art sleeve (e.g., as shown above) is simply a sleeve, with no locking mechanism.

(c) Claim 140 recites a locking mechanism which prevents both inward and outward longitudinal movement between the sleeve and the nail. For example, the specification of the present patent application states:

[0097] Fig. 3 is a schematic illustration of sleeve 50, in accordance with an embodiment of the present invention. Sleeve 50 comprises a locking mechanism 51, which engages head hole 36, preventing rotational and longitudinal movement between sleeve 50 and head hole 36. The locking mechanism typically comprises a male coupling element, such as a tab 52 fixed to the outer surface of a depressible tongue 54, which is adapted to flex inwards toward the center of the sleeve when pressure is applied thereto. When the pressure is removed, tab 52 engages female coupling element, such as a notch 72 of hole 36, as described hereinbelow with reference to Fig. 4A. It is noted that in embodiments of the present invention, prevention of rotational and longitudinal movement between sleeve 50 and head hole 36 is not obtained by simply pressure-fitting the sleeve in the hole, or by simply screwing the sleeve in the hole, either of which generally would result in gradual loosening of the sleeve over time.

[0098] Fig. 4A and 4B are cross-sectional illustrations of one of holes 36 of head 32 through the line B--B of Fig. 2A, in accordance with an embodiment of

the present invention. An inner grooved surface 70 of hole 36 is shaped to define a notch 72, which tab 52 engages when sleeve 50 is inserted into hole 36 and properly aligned, thereby locking sleeve 50 to hole 36. ... To insert sleeve 50 into hole 36 and engage locking mechanism 51, the surgeon typically first rotationally orients the sleeve so that tab 52 is aligned with a region of hole 36... The surgeon then rotates the sleeve so that tab 52 approaches notch 72. As tab 52 approaches notch 72, tab 52 (and tongue 54) is gradually depressed by inner surface 70, until the tab reaches the notch and the tongue springs back into its original position, forcing the tab into the notch, and locking it therein. Such a locking mechanism is generally impervious to loosening under cyclical loading, even over the course of many years. **By contrast, two pieces which are attached without a locking mechanism (e.g., by being screwed together or wedged together) are susceptible to gradual loosening over time.**

The Applicant notes that none of the prior art references of record actually prevent rotational and longitudinal motion of the sleeve with respect to the nail. Instead, the Applicant respectfully submits that the prior art references simply delay such rotational and longitudinal motion. Eventually, the Applicant notes, cyclic loading of structures which are held together by screws or by being wedged together causes the structures to loosen.

The Applicant believes that none of the references of record or otherwise known to the Applicant describe or suggest the apparatus of claim 155.

Claim 155 recites, *inter alia*, that the engagement of a locking mechanism of the sleeve, which is integral therewith, to the hole prevents longitudinal movement between the sleeve and the hole.

Lawes, for example, does not disclose, teach or suggest a sleeve having an integral locking mechanism which cooperates with a portion of the nail around the hole into which the sleeve is inserted in order to prevent longitudinal movement between the sleeve and the nail.

Support for the new claims is as described in the following table.

New claim	Support
140.	<p>Claim 1 as filed, with the following amendments as marked:</p> <p>[[1]] <u>140. Apparatus for treating a fracture of a bone of a subject, comprising:</u> an intramedullary (IM) nail, adapted to be inserted in a medullary canal of the bone of the subject, and comprising a proximal head that defines at least one hole therethrough, <u>the intramedullary nail having a locking surface shaped to</u></p>

	<p><u>define an indent</u>; and</p> <p>a sleeve, comprising a locking mechanism, which locking mechanism is adapted to engage the hole <u>indent of the locking surface of the intramedullary nail</u> when the sleeve is inserted in the hole, such engagement preventing rotational movement between the sleeve and the nail and preventing both inward and outward longitudinal movement between the sleeve and the nail.</p> <p>An example of a locking surface is notch 72 of hole 36, as shown in Figs. 2A, 2B, 4A, and 4B, and as described in the text:</p> <p>[0097] Fig. 3 is a schematic illustration of sleeve 50, in accordance with an embodiment of the present invention. Sleeve 50 comprises a locking mechanism 51, which engages head hole 36, preventing rotational and longitudinal movement between sleeve 50 and head hole 36. The locking mechanism typically comprises a male coupling element, such as a tab 52 fixed to the outer surface of a depressible tongue 54, which is adapted to flex inwards toward the center of the sleeve when pressure is applied thereto. When the pressure is removed, tab 52 engages female coupling element, such as a notch 72 of hole 36, as described hereinbelow with reference to Fig. 4A. ...</p>
141.	Claim 2 as filed.
142.	<p>Claim 3 as filed, with the following amendments as marked that conform claim 142 to the language of claim 140:</p> <p>[[3]] <u>142.</u> Apparatus according to <u>claim 140</u>, claim 1, wherein the proximal head is shaped so as to define a female coupling element located on a surface of the hole, and wherein the locking mechanism comprises a depressible male coupling element, configured to engage the female coupling element <u>indent</u> so as to prevent the rotational and longitudinal movement.</p>
143.	Claim 5 as filed.
144.	<p>Claim 6 as filed, with the following amendments as marked:</p> <p>[[6]] <u>144.</u> Apparatus according to claim 3, <u>claim 142</u>, wherein the depressible male coupling element is adapted to engage the female coupling element <u>indent</u> when the sleeve is inserted in the hole to a fixed depth and then rotated until the depressible male coupling element engages the female coupling element <u>indent</u>.</p>
145.	<p>[0097] FIG. 3 is a schematic illustration of sleeve 50, in accordance with an embodiment of the present invention. Sleeve 50 comprises a locking mechanism 51, which engages head hole 36, preventing rotational and longitudinal movement between sleeve 50 and head hole 36. <u>The locking mechanism typically comprises a male coupling element, such as a tab 52 fixed to the outer surface of a depressible tongue 54</u>, which is adapted to flex inwards toward the center of the sleeve when pressure is applied thereto.</p>

146.	Same as claim 145.
147.	<p>Claim 26 as filed, with the following amendments as marked:</p> <p>[[26]] 147. Apparatus for treating a fracture of a bone of a subject, comprising an intramedullary (IM) nail, adapted to be inserted in a medullary canal of the bone of the subject, the IM nail comprising a <u>according to claim 140, wherein the proximal head having has a distal portion and a proximal portion, the proximal portion visually discrete from the distal portion, the proximal portion adapted to aid in locating the IM nail, and the distal portion adapted to be coupled to at least one element.</u></p> <p>[0100] FIG. 5A is a schematic illustration of a head 132 of IM nail 30, in accordance with an embodiment of the present invention. In this embodiment, head 132 of IM nail 30 comprises a distal portion 180, which includes one or more head holes 136, and a proximal portion 182. Proximal portion 182 is adapted to aid in locating IM nail 30, while distal portion 180 is adapted to be coupled to at least one element, such as a nail, screw, or a sleeve. Proximal portion 182 is visually and structurally distinct from distal portion 180. Alternatively or additionally, proximal portion 182 has a diameter D_1 that is less than a diameter D_2 of distal portion 180 adjacent to proximal portion 182. For some applications, diameter D_1 is between 50% and about 80% of diameter D_2, or is less than about 50% of diameter D_2. For some applications, diameter D_1 is between about 25% and about 50% of diameter D_2. Typically, for IM nails intended for use in adults, diameter D_1 is between about 5 mm and about 10 mm, and diameter D_2 is between about 11 mm and about 17 mm. A length L_1 of proximal portion 182 is typically equal to between about 10% and about 50% of a length L_2 of head 132. For example, length L_1 may be between about 10 mm and about 35 mm, and length L_2 may be between about 40 mm and about 60 mm, in IM nails intended for use in adults. Although head 132 is shown in the figures as narrowing suddenly, for some applications the diameter of the head decreases gradually from D_2 to D_1. For some applications, such as for use in conjunction with the techniques, described hereinbelow with reference to FIGS. 6 or 7, (a) proximal portion 182 is removable, in which case the surgeon typically removes the proximal portion after implanting IM nail 30, or (b) head 132 does not comprise proximal portion 182, so that head 132 does not extend to the surface of femur 20.</p> <p>[0103] For some applications, IM nail 30 comprises both narrower proximal portion 182 and locking mechanism 51, as described hereinabove. ...</p>
148.	Claim 27 as filed.
149.	<p>Claim 7 as filed, with the following amendments as marked:</p> <p>[[7]] 149. Apparatus for treating a fracture of a bone of a subject,</p>

	<p>comprising an intramedullary (IM) nail, adapted to be inserted in a medullary canal of the bone of the subject, the IM nail comprising a <u>Apparatus according to claim 140, wherein the proximal head having has a distal portion and a proximal portion, the distal portion having a distal diameter, and the proximal portion having a proximal diameter less than or equal to about 80% of the distal diameter.</u></p> <p>Also, paragraphs [0100] and [0103] (as cited above with respect to new claim 147).</p>
150-152.	Claims 8-10 as filed, respectively.
153.	Paragraphs [0100] and [0103] (as cited above with respect to new claim 147).
154-155.	Claims 1, 96 and 125 as previously set forth. The sleeve 50 includes an integral locking mechanism 51 which has a tab 52 on a depressible tongue 54 (see Fig. 3). The tab 52 engages with a notch 72 in the portion of the nail 32 around the sleeve 50 (shown in Fig. 2B) when the sleeve 50 is inserted into the hole 36 in the nail 32.

No new matter has been added. The Applicant believes the amendments and remarks presented hereinabove to be fully responsive to all of the grounds of rejection and objection raised by the Examiner. In view of these amendments and remarks, the Applicant respectfully submits that all of the claims in the present application are now in order for allowance.

Entry of this Amendment, allowance of the claims and the passing of this application to issue are respectfully solicited.

If the Examiner has any comments, questions, objections or recommendations, the Examiner is invited to telephone the undersigned at the telephone number given below for prompt action.

Respectfully submitted,

/Leonard Holtz/

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